K043580

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c)

Submitted by:
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MAR 2 4 2005

Contact Person:
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Date summary prepared: 29 October 2004

Trade Name: Alligator™ Retrieval Device (ARD)

Common Name: Endovascular snare device

Classification Name: unknown

Device Description:
The Alligator Retrieval Device (ARD) is a retriever with grasping jaws attached to the tip of a flexible wire. The device is designed to be used in conjunction with off-the-shelf 0.21 in. (0.51mm) ID (inner diameter) microcatheter. The grasping jaws and the distal end of the ARD device are made of radio opaque material facilitating fluoroscope visualization. The ARD is for single use only.

Indications for Use:
The device is intended for use in the peripheral and neuro-vasculature for foreign body removal.

Predicate Devices:
Boston Scientific "In-Time" retriever
Microvena microsnare

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Comparision to Predicate Devices to Support Substantial Equivalence Determination:

The ARD is made of similar materials and has similar construction to the predicate devices listed above. Also, the ARD has substantially the same intended use as the predicate devices. Although the differences in construction and materials are incidental, the ARD was tested for biocompatibility. The ARD meets ISO 10993 for short-term (less than 24-hours) implantables, meets performance requirements of weld strength and force-to-open, and is provided sterile.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2005

Chestnut Medical Technologies, Inc.
c/o Ms. Patricia L. Murphy
KEMA Quality B.V.
4377 County Line Road
Chalfont, Pennsylvania 18914

Re: K043580
Trade/Device Name: Alligator™ Retrieval Device (ARD)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: DQY
Dated: March 8, 2005
Received: March 9, 2005

Dear Ms. Murphy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): Pending

Device Name: Alligator™ Retrieval Device (ARD)

Indications For Use: The Alligator Retrieval Device (ARD) is indicated for the use in retrieval of foreign objects in peripheral and neuro vasculature.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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